Contour® usb

BLOOD GLUCOSE MONITORING SYSTEM

NO CODING™

USER GUIDE

USES BAYER'S CONTOUR® BLOOD GLUCOSE TEST STRIPS

www.bayerdiabetes.co.uk

Bayer is committed to providing tools and services to make life simpler for people with diabetes. GLUCOFACTS® DELUXE software is installed on your CONTOUR® USB meter. Plug your meter into your computer for access to helpful reports of your stored data. You can change your meter settings to personalize the way you test, record and view your blood glucose results. Easy accuracy and helpful reports provided by Bayer with the CONTOUR USB meter and GLUCOFACTS DELUXE software are simple. With diabetes, simple wins.

Please keep this User Guide for your reference.

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Your CONTOUR® USB Blood Glucose Monitoring System:

The CONTOUR USB blood glucose monitoring system (meter, test strips and controls) is intended for self-testing by people with diabetes and by healthcare professionals to monitor glucose concentrations in whole blood.

⚠ ***CAUTION:*** The *MICROLET®2* lancing device included in the kit is not suitable for use by healthcare professionals. It must not be used on more than one person due to the risk of infection. Used test strips and lancets are a possible biohazard and must be disposed of properly.

Test Strip

Grey Electrode End: Insert this end into test strip port with grey end face up.

Sample Tip: Blood is drawn in here.

⚠ ***CAUTION:*** *Your CONTOUR USB meter **only** works with CONTOUR test strips!*

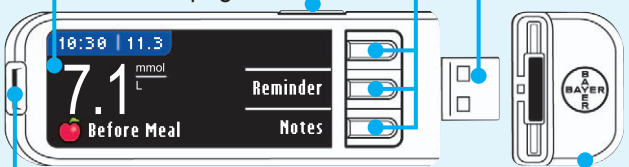
Meter Front

Display Screen

Menu Button: Provides access to features. See page 4.

Selection/Scrolling Buttons: See page 4.

USB Connector



Test Strip Port: Insert the test strip here. To turn on the port light, see page 11.

Protective USB Cap

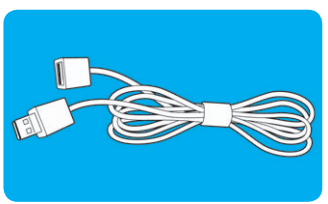
⚠ ***CAUTION:*** Keep out of reach of children. Accidental swallowing could cause suffocation.

Rechargeable Battery:

Your meter has a permanent rechargeable battery. **Before you do anything else,** charge your battery by plugging your CONTOUR USB meter into your computer. Make sure your computer is turned on and not in sleep, hibernate or power saving mode. Your meter will briefly display "Do Not Test-Charging" and the test strip port light will flash. For more details see page 52.

You cannot do a blood glucose test while the battery is charging. When charging is finished, the test strip port light will turn off. Unplug your CONTOUR® USB meter to test.

A USB extension cable is included for your convenience.



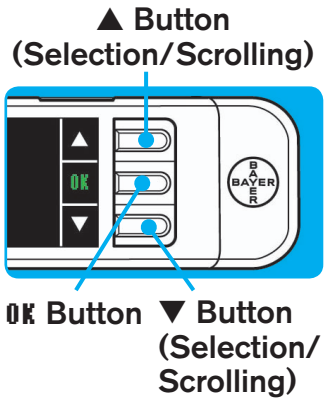
For more information on Battery Status Displays and Charging see pages 50-52.

Getting Started
Your CONTOUR® USB Blood Glucose Monitoring System

Meter Overview:

Using the Buttons –

Bayer's CONTOUR® USB meter is **simple** to use. Every screen gives you choices. The three buttons next to the screen allow you to make your selection by pressing the button next to your choice.

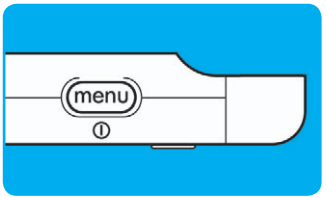


Using the Selection/Scrolling Buttons –

When the ▲ or ▼ arrows appear on the screen, the buttons are used for scrolling. When your choice is highlighted, make a selection by pressing the **OK** button. Pressing and holding the ▲ or ▼ buttons will scroll through the list faster.

Using the Menu Button –

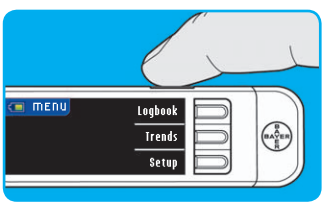
- **To turn on the meter and access the main menu, press and hold the Menu button until the meter turns on.**



The Main Menu has 3 choices: **Logbook**, **Trends** and **Setup**.

- Select one by pressing the button next to your choice.

- To **go back** to the previous screen, **press the Menu button once.**



- To turn the meter off, press and hold the Menu button for 2 seconds.
- To turn on the test strip port light with the meter off, press the Menu button twice with one second between each press. Press the Menu button twice to turn the light off.

Introducing AutoLog –

Your meter comes with a simple AutoLog feature that lets you mark your test result as **Before Meal** or **After Meal** during the 5 second test countdown. You can select **No Mark** if you are testing at times other than before or after a meal.

Your meter comes with AutoLog turned on. We recommend that you keep this feature turned on to get the most benefit from your meter features. AutoLog can be turned off in Setup.

To Run a Blood Glucose Test –

Read user guide and all instructional materials provided in your meter kit before testing.

To test, insert the CONTOUR® test strip and the meter will turn on.

Follow the on-screen prompts.

Remove the test strip to turn the meter off.

Extra Memory –

Your meter contains 500 MB extra memory.

Extra memory and GLUCOFACTS® DELUXE software require a high-power USB port. For more details see page 52.

We encourage you to plug your meter into computers with current anti-virus software installed and running.

NOTE: *Computer viruses cannot affect the blood glucose data on your CONTOUR® USB meter.*

GLUCOFACTS® DELUXE Data Management Software:

When you plug your CONTOUR® USB meter into your computer's USB port, follow your computer specific prompts to initiate GLUCOFACTS® DELUXE software.

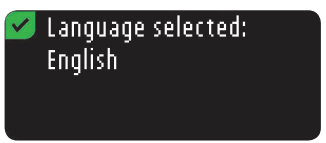
For more information see the GLUCOFACTS® DELUXE Quick Start Guide.

Initial Startup:

First charge your meter. Your computer can be used to perform initial startup while your meter is charging. You can also initiate setup directly on your meter once it is fully charged. When you first turn on your CONTOUR® USB meter, a setup sequence begins.

- **Press and hold the Menu button until the meter turns on.** After a welcome screen, you will see the Select Language screen.
- Press the ▲ or ▼ button to select your desired language. When highlighted, press the **OK** button.

A screen confirms your language.



On the next screen choose: **Quickstart** (see page 9), **Customize** (see page 10), or **Help**.

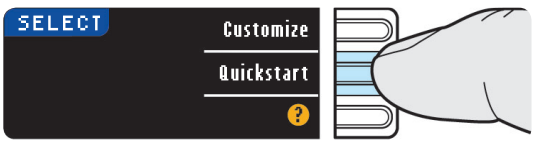
Quickstart – is set to the default settings. You will need to confirm the date and time, then you can immediately begin testing. You can also change these settings later.

Customize – allows you to adjust settings.
By default:
AutoLog is on;
Target is set to: Before Meal, 3.9 - 7.2 mmol/L
After Meal, 3.9 - 10.0 mmol/L
These settings can be changed in Setup.

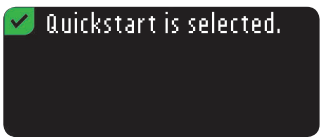
Help – provides additional information.

Initial Startup Using Quickstart:

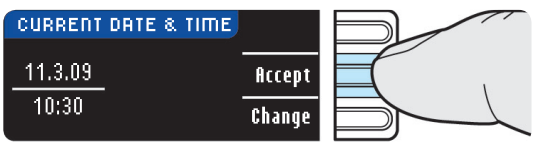
- Press the **Quickstart** button.



A screen confirms your choice.



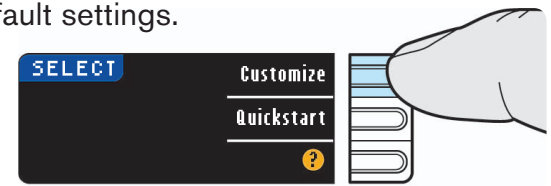
- The next screen has the current date and time. If it is correct press the **Accept** button. If incorrect, press the **Change** button (see pages 43–45).



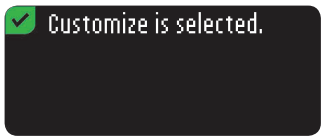
Setup is complete. You may now check your blood glucose.

Initial Startup Using Customise:

- Press the **Customize** button to change the default settings.



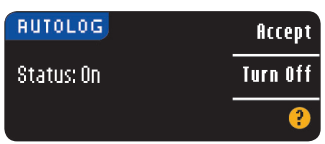
A screen confirms your choice.



- The next screen has the current date and time. If it is correct press the **Accept** button. If incorrect, press the **Change** button (see pages 43–45).

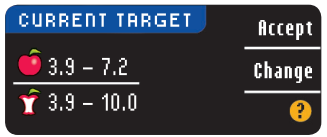
A screen confirms the date and time are set.

- The next screen shows that AutoLog is on. AutoLog lets you mark a test as Before Meal or After Meal during the 5 second test time.



To turn AutoLog off, see page 47.

- The next screen displays the default blood glucose target range for (Before Meal) and (After Meal) blood glucose.



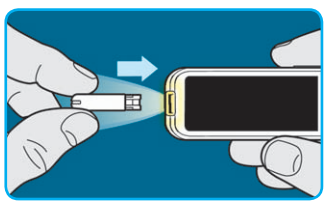
These values can be changed to the range you and/or your healthcare professional decide are your personal target ranges. You can accept the default ranges or change them by pressing the **Change** button (see page 48).

A screen confirms your target is set.

Setup is complete. You may now check your blood glucose.

Testing in the Dark:

Your meter has a test strip port light to help you test in the dark.



With the meter off, press the Menu button twice with one second between each press to turn on the test strip port light. Insert a test strip and the display screen will appear. Once blood is applied to the test strip the light will go off. Continue with your test.

Two quick presses of the Menu button will turn the light off.

Important Things to Know:

- ***Always keep the test strips in the original bottle. Tightly close the bottle immediately after removing a test strip.*** The bottle is designed to keep the test strips dry. Exposure to room humidity from leaving the bottle open or not storing them in the original bottle can damage your test strips.
- ***Do not drop blood directly on the flat surface of the test strip.*** Your test strip is designed to easily "sip" the blood into the sample tip.
- ***Do not press the test strip against your finger.*** This may block the sample tip.
- ***Test strips are for single use only.***
- ***Do not use a test strip that appears damaged or has been used.***
- ***Let the meter and test strips adjust to the temperature of the location where you are testing.*** Allow 20 minutes for the meter to adjust to the temperature of that new location before performing a blood glucose test. The products have been designed to give accurate results at temperatures between 5-45°C. Please be aware that USB ports in some computers and self-powered USB hubs can become much warmer than the room. A USB cable has been provided for your convenience. If you wish to test immediately after disconnecting from your computer, please use the USB cable.
- ***Check the expiry dates on your test strips and control solution.***

Important Note:

- *Your meter has been preset and locked to display results in mmol/L (millimoles of glucose per liter). In some countries, the meters are preset to display units in mg/dL (milligrams of glucose per deciliter);*
- *Results in mmol/L will **always** have a decimal point;*
- *Results in mg/dL will **never** have a decimal point.*

Example: $5.2\,\frac{mmol}{L}$ *or* $93\,\frac{mg}{dL}$

Check your screen to ensure that results are being displayed in mmol/L. If they are not, contact Bayer Diabetes Care Support Group, 0845 600 6030 (UK)/ 1 890 920 111 (Ireland).

Before You Begin Testing:

1. **Have your testing materials ready,** including your CONTOUR® USB meter, CONTOUR® test strips, and the MICROLET®2 lancing device with MICROLET® lancets. You may also need CONTOUR® control solution to run a quality control check.
2. **Wash your hands and "puncture site" thoroughly with warm soapy water and dry them well before testing.**

Getting Ready to Test:

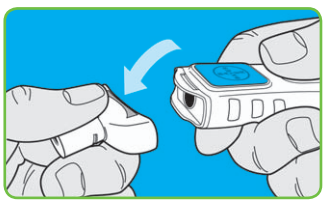
Read the MICROLET®2 insert for complete instructions. If you are using a different lancing device, refer to those instructions.

For Alternative Site Testing instructions, see page 18.

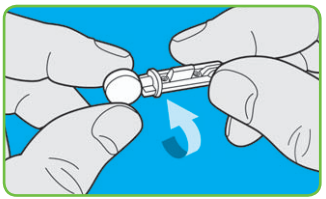
Potential Biohazard

⚠ **The MICROLET®2 lancing device is designed for self testing by a single patient. It must not be used on more than one person due to the risk of infection. Use a new MICROLET® lancet each time you test because it is no longer sterile after use.**

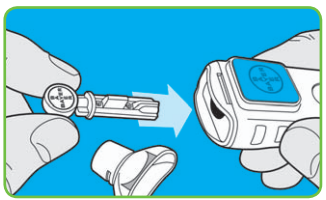
1. To remove the endcap, hold the device with your thumb on the grip indent and hold the endcap dial in the other hand. Snap the endcap off from top to bottom.



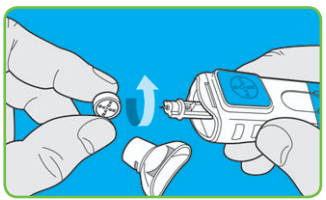
2. Loosen the round protective cap on a lancet by rotating it ¼ turn, but do not remove it.



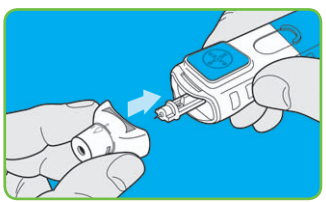
3. Insert the lancet firmly into the lancing device until it comes to a full stop.



4. Twist off the round protective lancet cap. Save it for disposing of the used lancet.



5. Replace the solid colour endcap.

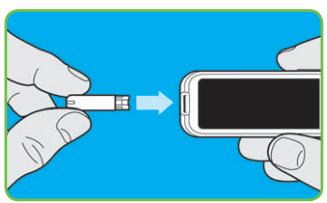


NOTE: *Your CONTOUR® USB meter codes itself every time you insert a test strip, so you do not have to worry about getting inaccurate results due to miscoding or forgetting to code your meter.*

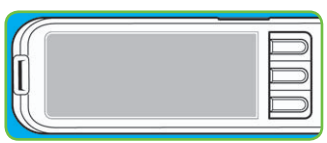
6. Remove a test strip from the bottle. **Tightly close the bottle lid immediately after you have removed the test strip.**

NOTE: *Check the expiry date. Make sure the test strip does not appear torn or damaged.*

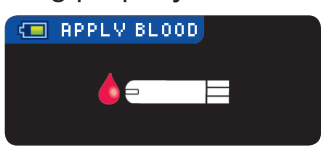
7. Hold the test strip with the grey end facing up.
8. Insert the grey end into the test strip port on the meter.



After the meter turns on, a solid **grey screen with a white border** will appear for one second to show that the screen is working properly.



The CONTOUR USB logo screen will briefly appear before the **Apply Blood** screen. The meter is now ready to test a blood drop.

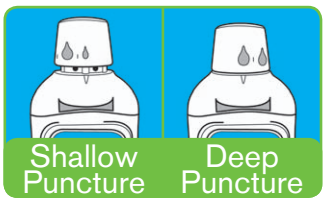


Getting the Blood Drop:

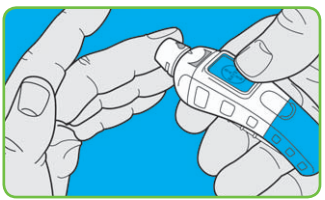
For fingertip testing

Use the ***Grey*** endcap

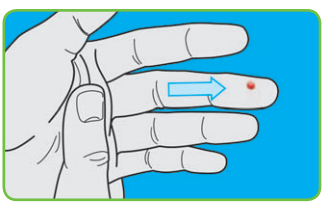
1. Rotate the endcap dial to adjust the puncture depth. The amount of pressure applied to the puncture site also affects puncture depth.



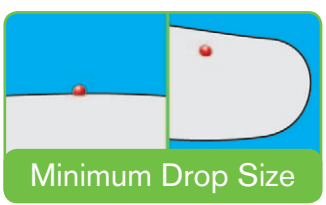
2. Press the endcap firmly against the puncture site and press the blue release button with the Bayer logo.



3. Stroke your hand and finger towards the puncture site to form a drop of blood. Do not squeeze around the puncture site.



4. Test immediately after you have formed a small, round blood drop (0.6 µL).



If you selected fingertip testing, turn to page 22 to continue reading testing instructions.

For Alternative Site Testing (AST)

IMPORTANT: Do not use Alternative Site Testing under the following conditions. Use fingertip testing in any of these cases:

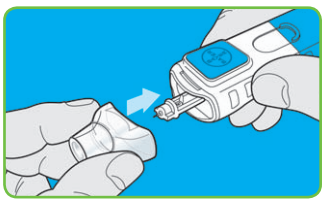
- **If you think your blood glucose is low (hypoglycaemia).**
- **When blood glucose is changing rapidly (after a meal, insulin dose or exercise).**
- **If you have hypoglycaemic unawareness (lack of symptoms).**
- **If you get alternative site blood glucose results that do not agree with how you feel.**
- **During illness or times of stress.**
- **If you will be driving a car or operating machinery.**

Consult your healthcare professional to determine if alternative site testing is right for you.

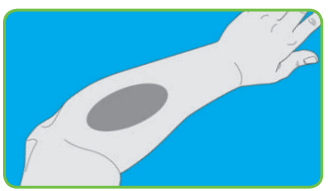
Alternative Site Testing (AST) is recommended only when it is more than two hours after a meal, diabetes medication, or exercise.

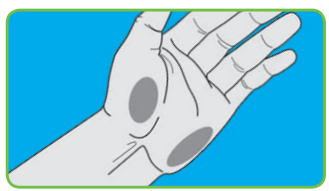
Use the ***Clear*** endcap

1. Attach the **clear** AST endcap to the MICROLET®2 lancing device.

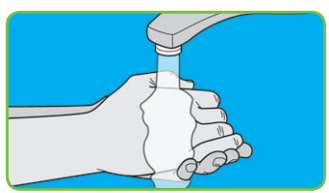


2. Select a puncture site from a fleshy area on forearm or palm. Avoid veins, hair, moles, bones, and tendons.



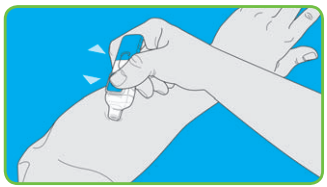


3. Wash your hands and the puncture site with soap and warm water. Rinse and dry thoroughly.



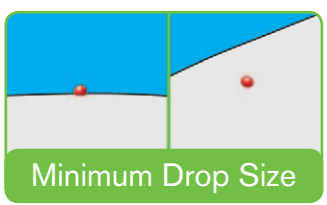
For forearm testing:

1. Rub the testing area vigorously until it feels warm to increase blood flow.

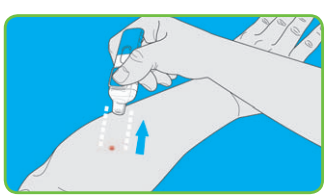


2. Press the **clear** endcap firmly against the puncture site and then press the blue release button. Keep the device in constant contact with the skin and pump (apply and release pressure) up and down 2–3 times **without lifting the device away from the skin.**

3. Maintain steady pressure until a small round blood drop forms.

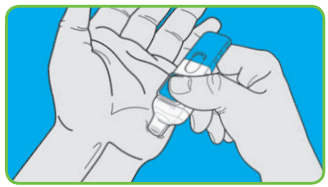


4. Lift the device straight up and away from the skin without smearing the blood.

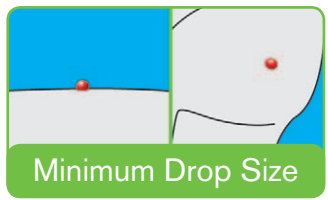


For palm testing, it is not necessary to rub the skin or pump the device up and down.

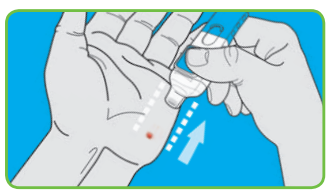
1. Press the **clear** endcap firmly against the puncture site and then press the blue release button.



2. Maintain steady pressure until a small, round blood drop forms.



3. Lift the device straight up and away from the skin without smearing the blood.



Do not test the blood sample from palm or forearm if you get: Smeared blood • Clotted blood • Runny blood • Clear fluid mixed with the blood.

Collecting Your Blood Drop:

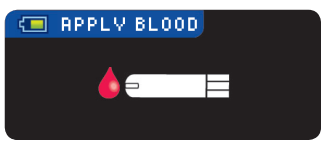
1. Immediately touch the **tip** of the test strip to the drop of blood.* The blood is drawn into the test strip tip.
2. **Hold the tip of the test strip in the blood drop until the meter beeps.**

Do not press the tip against the skin or place the blood on top of the test strip.

Forearm

Palm

***NOTE:** **If you do not apply blood to the test strip in 1 minute**, the meter screen will dim and the meter beeps. Press any button and the **Apply Blood** screen will become active again. After a total of 3 minutes of inactivity the meter turns off.



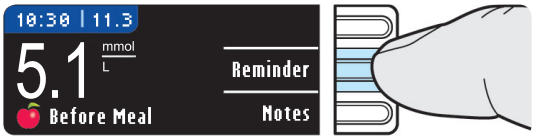
Testing with AutoLog On:

Before your test result is displayed, the AutoLog screen appears. **Select Before Meal, After Meal or No Mark by pressing the button next to it. Your test result will not display until you make a selection.** However, if your result is a low blood glucose result or high blood glucose result, you will always see your result in 5 seconds.

Your meter features a 5 second test time. If you make your selection in less than 5 seconds, you will see the remainder of the testing countdown.

Your test result is displayed in large numbers for 2 seconds before changing to the normal test result screen. For results under 0.6 mmol/L or over 33.3 mmol/L, see page 26.

You can now set an optional **Reminder** (see page 32) or add a **Note** (see page 39).



Remove the test strip to turn the meter off.

Potential Biohazard

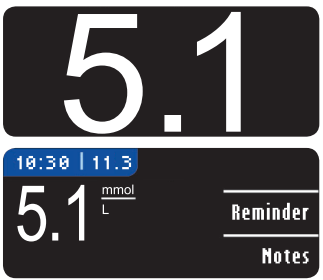
⚠ **Always dispose of test strip and lancet properly. All products that come in contact with human blood should be handled as if capable of transmitting viral diseases.**

Please refer to your MICROLET®2 lancing device package insert for instructions on how to properly remove and dispose of the lancet.

Testing with AutoLog Off:

After applying blood to the test strip when AutoLog is turned off, the testing countdown screen appears for the 5 second countdown.

Your test result is displayed.



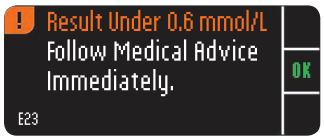
You may add a Note or Reminder. Please see pages 32 and 39 for further instructions.

Test Results:

Expected Values: Blood glucose values will vary depending on food intake, medication dosages, health, stress, or activity. Non diabetic expected values are 3.9 to 7.2 mmol/L fasting.[1] **You should consult with your healthcare provider for expected values specific to your needs.**

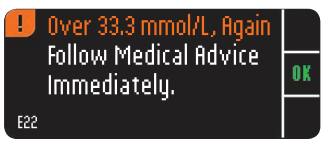
High and Low Blood Glucose Alert Screens:

- If your blood glucose reading is under 0.6 mmol/L the normal screen sequence will appear for 5 seconds. The "Follow Medical Advice Immediately" screen will then display and the meter will beep twice.



- If your blood glucose reading is over 33.3 mmol/L the normal screen sequence will display for 5 seconds and the next screen will tell you to retest. The meter will beep twice.

- If results are still over 33.3 mmol/L, "Follow Medical Advice Immediately" is displayed.



⚠ CAUTION:

- ***If your blood glucose reading is under 2.8 mmol/L follow medical advice immediately.***
- ***If your blood glucose reading is over 13.9 mmol/L repeat the test. If you get a similar result, call your healthcare professional immediately.***
- ***Do not change your medication based on CONTOUR® USB blood glucose results without the advice of your healthcare professional.***

High and Low Blood Glucose Readings:

Your meter has been preset with a hypoglycaemic (low blood glucose) value of 3.9 mmol/L and a hyperglycaemic (high blood glucose) value of 13.9 mmol/L. These are the default values, but can be customised by you and/or your healthcare professional using the **GLUCOFACTS® DELUXE software** on your computer. See the GLUCOFACTS® DELUXE Quick Start Guide for assistance.

Low Blood Glucose

If your blood glucose reading is under 3.9 mmol/L:

- A screen with large orange numbers will alert you that your blood glucose is low.

High Blood Glucose

If your blood glucose reading is over 13.9 mmol/L:

- A screen with large orange numbers will alert you that your blood glucose is high.

- If AutoLog is on and you were not able to mark it before the high or low alert appeared, press the **Notes** button. You may now select **Before Meal**, **After Meal** or **No Mark** by pressing the button next to it.

Symptoms of High and Low Blood Glucose:

You can better understand your test results by being aware of the symptoms of high or low blood glucose; this will also help you decide what to do if your results seem unusual.

Some of the most common symptoms are:[2]

High blood glucose (Hyperglycaemia):
- frequent urination
- excessive thirst
- blurred vision
- increased fatigue
- extreme hunger
- irritability

Low blood glucose (Hypoglycaemia):
- shakiness
- hunger
- sweating
- fast heartbeat
- blurred vision
- confusion
- passing out
- seizure

Ketones (Ketoacidosis):
- shortness of breath
- nausea and vomiting
- very dry mouth

⚠ ***CAUTION:* Blood glucose levels below 2.8 mmol/L or above 13.9 mmol/L may indicate a potentially serious medical condition. If your test result is below 2.8 mmol/L or above 13.9 mmol/L, consult a healthcare professional immediately.**

For additional information and a complete list of symptoms, contact your healthcare professional.

Performing a Control Test:

You should perform a control test:

- When using your meter for the first time
- To check if you are testing correctly
- When you open a new vial of test strips
- If you leave the test strip vial open for an extended period of time
- If you think your meter may not be working properly
- If your test results do not match how you feel

Low, Normal and High control solutions are available. **Always use CONTOUR® control solutions, as other brands could present incorrect results.**

1. Remove a test strip from the bottle and **firmly snap the lid closed.**

NOTE: *Check the expiry date and discard date on the control bottle. Make sure the test strip does not appear torn or damaged.*

2. Prepare to run a control test by inserting a test strip into the meter.
3. Gently rock the control bottle before opening to ensure it is mixed well.
4. Squeeze a small drop of control solution on a clean non-absorbent surface, such as a piece of wax paper. **Do not apply control solution to the test strip directly from the bottle.**

5. Replace the cap on the control solution bottle.
6. Immediately touch the **tip** of the test strip to the drop of control solution.
7. Hold it in the drop until the meter beeps.

Even when AutoLog is on, there is no need to mark the control test. In 5 seconds the meter displays the control test result.

8. Compare your control test result with the Normal Control range printed on the test strip bottle label or on the bottom of the test strip box.

The Low and High control range values can be found printed on the test strip bottle label or on the bottom of the test strip box.

If your control test result falls out of the specified range, call the Bayer Support Group, 0845 600 6030 (UK)/ 1 890 920 111 (Ireland). Do not perform any blood glucose tests until you resolve this issue.

The result will automatically be marked as a control test and stored in the meter memory. Control results will not be included in your blood glucose average. To turn your meter off, simply remove the test strip.

Setting a Reminder:

A Reminder for your next test can be set after testing or from the Setup menu.

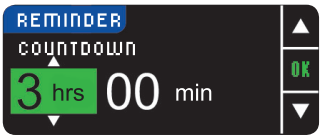
After Testing:

1. Press the **Reminder** button.

2. Press the **Start** button to begin the countdown. The default time is 2 hours or the last reminder time that was set.

You can change the Reminder countdown time to the time you wish by pressing the **Change** button.

1. Press the ▲ or ▼ button to select the correct hours. Press the **OK** button.

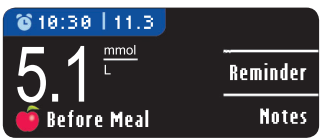


2. Press the ▲ or ▼ button to select the minutes. Minutes change in 15 minute increments. Press the **OK** button.

A screen confirms the Reminder countdown time.

The meter will return to the test result screen.

When the Reminder feature is on, the clock symbol is in the blue header.



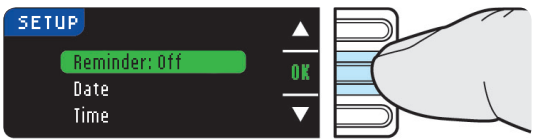
3. Remove the test strip from the meter.

The meter retains the Reminder time that you set as the default.

From the Setup Menu:

1. Go to the Main Menu. Press the **Setup** button.

2. If Reminder is set to off, press the **OK** button to change the Reminder settings.



3. To start the countdown press the **Start** button or press the **Change** button to scroll to a different countdown time. Follow the instructions on the previous page.

A screen confirms the Reminder time set.

When the Reminder feature is on, the clock symbol is in the blue header.

Turning Off a Reminder:

A Reminder can be turned off or changed after testing or from the Setup menu.

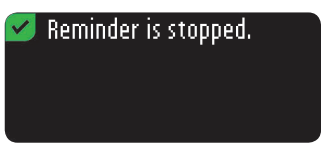
After Testing:

1. Press the **Reminder** button.

If the countdown is currently on, the screen will read “Reminder In:” with the remaining amount of time displayed.

2. To stop the Countdown press the **Stop** button.

A screen confirms your choice.



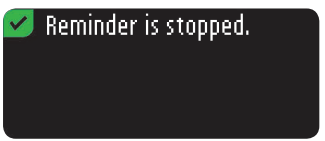
The Countdown is now stopped and the clock symbol will disappear.

From the Setup Menu:

1. Press the **OK** button.

2. Press the **Stop** button. The countdown is now stopped. The Reminder screen displays the remaining time.

A screen confirms your choice.

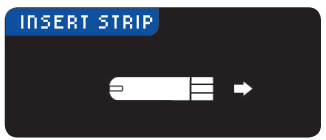


Getting a Reminder:

When the Reminder time is reached, 20 beeps will sound. The meter will turn on and a Reminder screen will appear. You can stop the beeps by pressing the **OK** button or inserting a test strip.

1. Press the **OK** button.

2. Proceed with testing (see page 14).

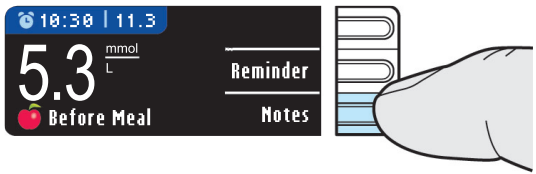


If you are testing when the Reminder countdown time is within 15 minutes of the reminder, neither screen will appear and the countdown will be stopped.

Adding Notes:

You may add **Notes** to your test result that may help explain results. Your notes will be saved in the Logbook.

1. From the test result screen, press the **Notes** button.



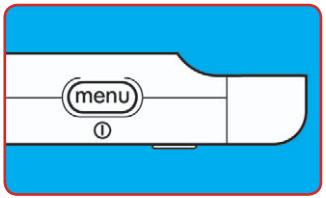
2. Press the ▲ or ▼ button to scroll through the choices. Some may not be visible until you scroll up or down. Press the **OK** button when your choice is highlighted.

A screen confirms your choice.

After the confirmation screen disappears, you may add additional Notes by repeating the steps above. The notes will scroll across the bottom so that you can read them all.

Menu Button:

- **To turn on the meter, press and hold the Menu button until the meter turns on.**



The Main Menu has 3 choices: **Logbook**, **Trends** and **Setup**.

- Select one by pressing the button next to your choice.
- To go back a screen, press the Menu button once.
- To turn the meter off, press and hold the Menu button for 2 seconds.
- To turn the test strip port light on with the meter off, press the Menu button twice with one second between each press. Press the Menu button twice to turn the light off.

Logbook:

To access the Logbook, press the Logbook button from the Main Menu.

In Logbook you can scroll through all the stored test results in memory by pressing the ▲ or ▼ button.

The most recent result is shown first and the oldest result last. When you reach the oldest entry you will see the End of Logbook screen. Your meter will store 2000 test results.

Trends:

1. Press the **Trends** button to view averages.

14 days is the default. To change the averages to 7 or 30 days, plug the meter into your computer and **set using GLUCOFACTS® DELUXE software.**

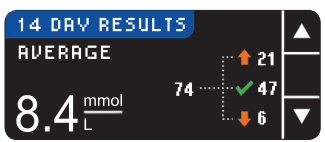
If AutoLog is on, the default (Before Meal) and (After Meal) target ranges will appear. To set personalised target ranges, see page 48.

The next three screens will show 14 day Before Meal, 14 day After Meal and 14 day total average. Also shown are the total number of test results included in the average, the number of tests ⬆ (above), ✓ (within) and ⬇ (below) target.

2. Press the ▼ button to display the 14 Day Before Meal Average. This example shows that your Before Meal average is 7.1 mmol/L and 38 test results are included in the Before Meal average with 26 in the ✓ target range, 8 ⬆ over your target range and 4 ⬇ under the target range.

3. Press the ▼ button to go to the 14 Day After Meal Average.

4. Press the ▼ button to go to the 14 Day Results screen.



NOTE: *If you turn off AutoLog, only the 14 Day Results total will display.*

Setup:

Setting the Date –

1. Press the Menu button to go to the Main Menu.

2. Press the **Setup** button.

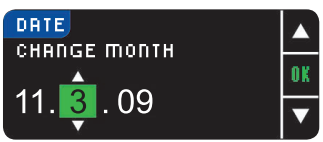
3. Press the ▲ or ▼ button to select Date. Press the **OK** button.

4. To change the date, press the **Change** button.

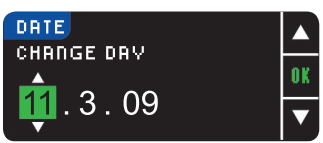
5. Select either the **Month/Day/Year** or **Day.Month.Year** button.

6. Press the ▲ or ▼ button to select the correct year. Press the **OK** button.

7. Press the ▲ or ▼ button to select the correct month. Press the **OK** button.



8. Press the ▲ or ▼ button to select the correct day. Press the **OK** button.

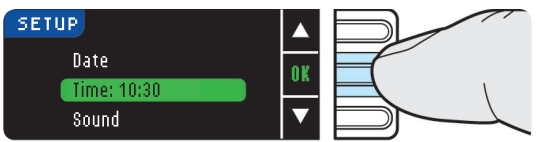


A screen confirms the date you entered. If correct, press the **Done** button and the Setup menu will appear.

If you need to make changes, press the **Change** button and repeat the process.

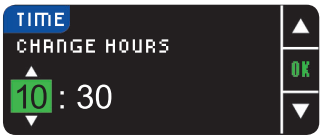
Setting the Time –

1. Press the Menu button to go to the Main Menu.
2. Press the **Setup** button.
3. Press the ▲ or ▼ button to select Time. Press the **OK** button.



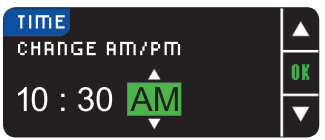
4. To change the time, press the **Change** button.
5. Select either the **12 hour clock** or **24 hour clock** button.

6. Press the ▲ or ▼ button to select the correct hour. Press the **OK** button.



7. Press the ▲ or ▼ button to select the correct minute. Press the **OK** button.

8. Press the ▲ or ▼ button to select the correct AM/PM. Press the **OK** button.



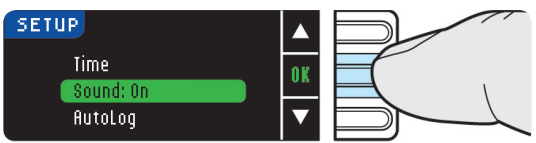
A screen confirms the time you entered. If correct, press the **Done** button and the Setup menu will appear.

If you need to make changes, press the **Change** button and repeat the process.

Turning the Sound On/Off –

Sound is turned ON when you receive your meter. It can be turned off using the Setup menu. Certain error messages and the Reminder bell will override the Sound off setting. One long beep indicates a confirmation. Two beeps indicate an error or situation that requires your attention.

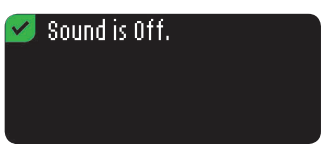
1. Press the Menu button to go to the Main Menu.
2. Press the **Setup** button.
3. Press the ▲ or ▼ button to select Sound. Press the **OK** button.



4. To turn the sound off, press the **Turn Off** button.

   To keep the sound on, press the **Go Back** button.

A screen confirms that sound is off. The Setup menu will appear.



Turning *AutoLog* On/Off –

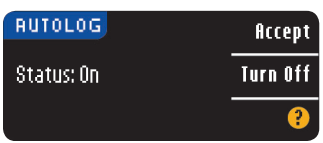
The AutoLog feature lets you mark your test result as Before Meal or After Meal during the 5 second test countdown. You can select No Mark if you are testing at times other than before or after a meal. Your meter comes with AutoLog turned on. We recommend that you keep this feature turned on.

Note: *When AutoLog is ON, a result will not appear unless marked as Before Meal, After Meal, or No Mark; or if the result is outside the High/Low ranges.*

1. Press the ▲ or ▼ button to select AutoLog. Press the **OK** button.

2. To turn the AutoLog off, press the **Turn Off** button.

   To keep the AutoLog on, press the **Accept** button.



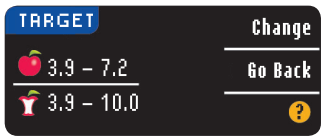
A screen confirms that AutoLog is off. The Setup menu will appear.

Changing the Blood Glucose Target Range –

Your CONTOUR® USB meter comes preset with 3.9-7.2 mmol/L for Before Meal testing and 3.9-10.0 mmol/L for After Meal testing. Ranges can be changed to personal targets decided by you and/or your health-care professional. **Use GLUCOFACTS® DELUXE software to make such changes.**

1. Press the Menu button to go to the Main Menu.
2. Press the **Setup** button.
3. Press the ▲ or ▼ button to select **Target**. Press the **OK** button.

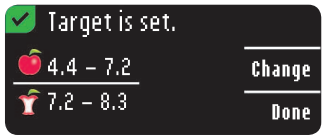
4. To make changes to your target range, press the **Change** button, otherwise **Go Back**. Press ? for **Help**.



5. Press the ▲ or ▼ button to select your desired **(Before Meal)** low target. Press the **OK** button.

Repeat this process to set your personal **(Before Meal)** high target and **(After Meal)** low and high targets. Press the **OK** button after each selection.

A screen confirms that all target ranges are set. If correct, press the **Done** button. You will be returned to the Setup menu.

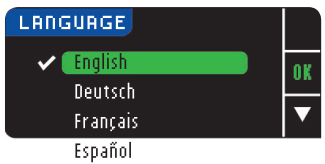


To make changes, press the **Change** button and repeat the process.

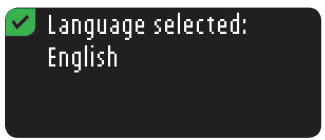
Setting the Language –

1. Press the Menu button to go to the Main Menu.
2. Press the **Setup** button.
3. Press the ▲ or ▼ button to select **Language**. Press the **OK** button.

4. Press the ▲ or ▼ button to select the language you prefer. Press the **OK** button.



A screen confirms your choice. The Setup menu will appear in the language you selected.



Error Detection Displays:

An error screen will always have an "E" with a number in the lower left hand corner of the display.

If there is an error (hardware, software, testing errors) detected by your meter then your meter will beep twice. You will see specific instructions to guide you. The first line of the error screen will tell you what the error is. The next lines describe what you should do. When an error screen has an **OK** shown, press the button next to it to continue.

Battery Status Displays:

The battery status will be displayed with a battery symbol on the Apply Blood screen and the Main Menu screen. It shows how much battery life is left. This screen displays full battery.

As the battery is used, the battery symbol on the screen gradually shows less fill colour. The colour of the battery fill turns yellow when the battery is low and then red when your battery is almost out of charge.

A series of low battery alerts will tell you that the battery is low and to charge soon.

If you do not charge the battery, a display will alert you Shutting down, Battery is dead. Charge immediately.

Plug the meter into your computer. Be sure your computer is turned on and not in sleep, hibernate or power save mode. Please be aware that USB ports in some computers and self-powered USB hubs can become much warmer than the room. A USB cable has been provided for your convenience. If you wish to test immediately after disconnecting from your computer, please use the USB cable.

The test strip port light will flash during charging and stop flashing when charging is complete. Please remove the meter and store in the wallet until you are ready to test.

Error Detection and Battery Status/Charging/Removal

Technical, Service & Care

Battery Charging:

When you plug your meter into the USB port, it will start to charge immediately. While the battery charges, the strip port light flashes slowly.

Press the Menu button at any time to display the charging status.

Rapid Charge

If the battery is low when you plug in your meter, it will Rapid Charge for about 1 minute. You can run a blood glucose test as soon as Rapid Charge is complete.

Normal Charging

When Rapid Charge ends, normal charging is expected to last up to 2 hours. When the battery is full, the strip port light turns off.

NOTE: *A high-power USB port will allow you to access GLUCOFACTS® DELUXE and your meter's extra memory. It also allows the shortest charging time. If the charging status displays "Low Power Charging," your CONTOUR USB meter may not be plugged into a high-power USB port. Please try a different USB port on your computer. If you are unsure whether your computer has a high-power USB port, please check with your computer user manual or the computer manufacturer.*

Extra Memory:

Your meter contains 500 MB extra memory. It appears on your computer as a "Removable Disk" when you insert your meter into the USB port. You can use this memory while your battery is charging. When you read or write to the memory, the strip port light flashes quickly.

Wall Charger:

For information about a wall charger, please call the Bayer Support Group at 0845 600 6030 (UK)/ 1 890 920 111 (Ireland) or visit www.bayerdiabetes.co.uk.

Error Detection and Battery Status/Charging/Removal

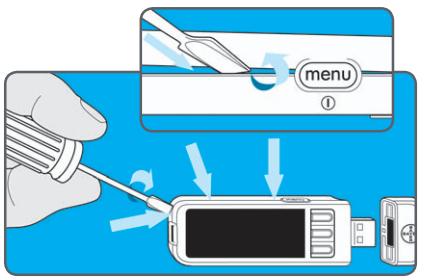
Technical, Service & Care

End of Meter Life/Battery Removal:

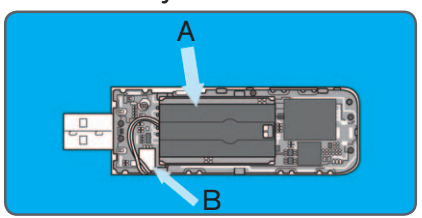
***NOTE:* Carry out this process only when you no longer intend to use the meter. Meter will not be functional once opened to remove the battery.**

To remove the battery for proper disposal, you will need to pry the upper and lower cases apart.

With a screwdriver, beginning near the strip port, insert the tip of the screwdriver and twist to pry the case loose. Continue to do this down the side until the upper case comes apart.



Pry off the black plastic cover over the battery (A). Disconnect the battery from the connector (B).



Dispose of the meter and lithium polymer battery in accordance with your local/ country laws and regulations.

System Performance Information:

Intended Use:

The CONTOUR® USB system (meter, test strips and control) is intended for self-testing by people with diabetes to monitor glucose concentrations in whole blood. Capillary samples may be drawn from alternative site testing locations. The test provides a quantitative measurement of glucose in blood from 0.6-33.3 mmol/L.

The CONTOUR USB system is not indicated for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

⚠ ***CAUTION:***

- ***For in vitro diagnostic use only.***
- ***Potential Biohazard:***
  The CONTOUR USB meter is intended for use with only one person. All products or objects that come in contact with human blood, even after cleaning, should be handled as if capable of transmitting viral diseases.[3]

Principles of the Procedure:

The CONTOUR® blood glucose test is based on measurement of electrical current caused by the reaction of glucose with the reagents on the electrode of the strip. The blood sample is drawn into the tip of the test strip through capillary action. Glucose in the sample reacts with FAD glucose dehydrogenase (FAD-GDH) and potassium ferricyanide. Electrons are generated, producing a current that is proportional to the glucose in the sample. After the reaction time, the glucose concentration in the sample is displayed. No calculation is required.

Limitations:

- **Preservatives:** Blood may be collected by healthcare professionals into test tubes containing heparin. Do not use other anticoagulants or preservatives.
- **Altitude:** Up to 3048 meters does not significantly affect results.
- **Lipemic Specimen:** Cholesterol concentrations >12.9 mmol/L or triglyceride concentrations >34.3 mmol/L may produce elevated readings.
- **Peritoneal dialysis solutions:** Icodextrin does not interfere with CONTOUR® test strips.
- **Xylose:** Do not use during or soon after xylose absorption testing. Xylose in the blood will cause an interference.
- **Contraindications:** Capillary blood glucose testing may not be clinically appropriate for persons with reduced peripheral blood flow. Shock, severe hypotension, hyperosmolar hyperglycaemia and severe dehydration are examples of clinical conditions that may adversely affect the measurement of glucose in peripheral blood.[4]
- **Interference:** Reducing substances occurring in the blood naturally (uric acid, bilirubin) or from therapeutic treatments (ascorbic acid, paracetamol) will not significantly affect results. The limiting concentrations of these compounds are listed in your test strip insert.

System Requirements:

Windows®: XP SP3, Vista SP2
Mac: OS® X v10.5.2 (Intel® 64 bit processors only)
High-Power USB port
Java 1.6.0_07 or higher
For latest compatibility: www.bayerdiabetes.co.uk

Precision and Accuracy Summary:

Accuracy: The accuracy of the CONTOUR® USB blood glucose monitoring system has been assessed in a correlation study conducted by healthcare professionals. In this study 100 fresh capillary blood specimens were tested with the CONTOUR USB blood glucose monitoring system by 100 untrained people with diabetes using three test strip lots. The reference measurement was done on the YSI™ Glucose analyzer. CONTOUR USB data compare well with the results from the YSI method.

Regression Statistics (Plasma/Serum Reference): plasma reference glucose range: 3.22 mmol/L to 22.86 mmol/L

Lot	y =	Correlation Coefficient (r)
1	0.97x + 0.25 mmol/L	0.975
2	1.04x – 0.23 mmol/L	0.971
3	1.01x + 0.15 mmol/L	0.979

Precision: A study was conducted with the CONTOUR USB blood glucose monitoring system with five heparinized whole blood specimens with glucose levels from 2.33 mmol/L to 18.9 mmol/L. Multiple replicates (n=100) were tested using multiple CONTOUR® USB blood glucose meters and one lot of CONTOUR® blood glucose test strips. The following precision results were obtained.

Plasma/Serum:

Mean	SD	Coefficient of variation
2.44 mmol/L	0.06 mmol/L	2.4%
4.66 mmol/L	0.08 mmol/L	1.7%
7.33 mmol/L	0.10 mmol/L	1.3%
11.32 mmol/L	0.19 mmol/L	1.7%
18.43 mmol/L	0.21 mmol/L	1.2%

Service Information:

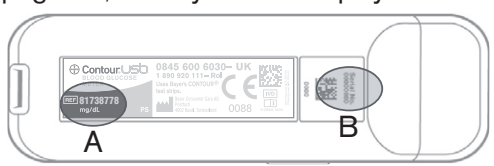
If you have a problem and none of the problem solving messages on the meter help, call Bayer Diabetes Care Support Group at: 0845 600 6030 (UK)/ 1 890 920 111 (Ireland). We have trained specialists to help you.

Important:
Speak to a Bayer Diabetes Care Support Group Representative before returning your meter for any reason. He/she will give you the information needed to get your problem handled correctly and efficiently.

Have your CONTOUR® USB blood glucose meter and CONTOUR® test strips available when you phone. It would also be helpful to have a bottle of CONTOUR® control solution nearby.

Check List:
This check list may be helpful when speaking with Bayer Diabetes Care Support Group:

1. Locate the model number (A) and serial number (B) on the back of the meter. _____
2. Locate the test strips' expiry date on the bottle. _____
3. Check the battery symbol on the screen. (See page 50, Battery Status Displays and Charging.)



Symbols Used:

The following symbols are used throughout the product labeling for the CONTOUR® USB Blood Glucose Monitoring System (meter packaging and labeling, test strip packaging and labeling and control solution packaging and labeling).

- Expiry date (use by last day of month)
- LOT — Batch code
- 5°C–45°C — Temperature limitations
- Consult instructions for use
- IVD — *In vitro* diagnostic device
- Manufactured by
- Caution, consult accompanying documents
- REF — Product code number
- CONT L — Control Range Low
- CONT N — Control Range Normal
- CONT H — Control Range High
- Green Dot® Packaging Recovery Directive
- Do Not Re-use
- Batteries must be disposed of in accordance with laws in your country. Contact your competent local authority for information on the relevant laws regarding disposal and recycling in your area.

The meter should be treated as contaminated and disposed of according to local safety rules. It should not be disposed of with waste electronic equipment.

Specifications:

Test Sample: Whole blood
Test Result: Referenced to plasma/serum glucose
Sample Volume: 0.6 µL
Measuring Range: 0.6–33.3 mmol/L
Measuring Time: 5 seconds
Memory: Stores most recent 2000 test results
Battery Type: Non-serviceable, 280mAh rechargeable lithium polymer battery, 3.4-4.2v (5V input voltage)
Meter / Battery Life: 5 years
Charging Current: 500 mAh
Charging Temperature: 0°–35°C
Shipping, Storage and Operating Temperature Range: 5°–45°C
Humidity: 10–93% RH
Dimensions: 97 mm (H) x 30 mm (B) x 16 mm (T)
Weight: 43 grams
Sound: A beep sounds when the meter is turned on or off, a test strip is inserted, when a test strip is filled with blood, or when a test result appears on the screen. Two beeps sound when a strip is removed and the meter is turned off, or to alert the user. Twenty beeps will sound when a programmed Reminder sounds.
Extra Memory: 1 GB portable flash drive with 500 MB user-accessible partition.
Emissions: CONTOUR® USB complies with the electromagnetic requirements specified in ISO 15197. Electromagnetic emissions are low and unlikely to interfere with other nearby electronic equipment, nor are emissions from nearby electronic equipment likely to interfere with CONTOUR USB. Immunity to electrostatic discharge meets the requirements of IEC 61000-4-2. It is advisable to avoid use of electronic devices in very dry environments especially if synthetic materials are present.
CE Certification: The CONTOUR USB system meets all the requirements of 98/79/EC for *In Vitro* Diagnostic Devices.

Caring for Your Meter:

- ***CAUTION:*** *Only connect to a computer or charger that is certified to UL 60950-1, 5V maximum. A charging current of 500 mAh minimum is required.*
- If you use a cable, use the one provided in your meter kit.
- Store your meter in the carrying case provided whenever possible.
- Wash hands and dry them thoroughly before handling to keep the meter and test strips free of oils and other contaminants.
- Handle the meter carefully to avoid damaging the electronics or causing other malfunctions.
- Avoid exposing meter and test strips to excessive humidity, heat, cold, dust, or dirt.
- The exterior of the meter can be cleaned using a moist (not wet) lint-free tissue with a mild detergent or disinfectant solution, such as 1 part bleach mixed with 9 parts water. Wipe dry with lint-free tissue after cleaning. Do not insert anything into or attempt to clean inside the USB connection or test strip port.

⚠ ***CAUTION: Do not allow cleaning solution to run in or around the buttons, USB cap, or strip port. Doing so may cause a malfunction.***

- The USB cap of your CONTOUR USB meter is designed to protect the USB port. Should you lose the cap, call the Bayer Support Group at 0845 600 6030 (UK)/ 1 890 920 111 (Ireland).

Supplies:

When calling or writing for supplies make sure you include the number with the name of the replacement part or accessory item.

REPLACEMENT PARTS

Part Number*	Item
82259989	CONTOUR® USB User Guide
81363014	Bayer's USB Extension Cable
81675369	USB Cap

*Part numbers are subject to change without notice.

References:

1 Fauci, A. *et al.:* Principles of Internal Medicine-17th Edition, 2008.

2 American Diabetes Association, www.diabetes.org

3 Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline–Third Edition. Clinical and Laboratory Standards Institute (CLSI), document M29-A3, (ISBN 1-56238-567-4). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2005.

4 Atkin, S. *et al.:* Fingerstick Glucose Determination in Shock. *Ann. Int. Med. 114*:1020-24; 1991.

Warranty:

Manufacturer's Warranty: Bayer Diabetes Care warrants to the original purchaser that this instrument will be free from defects in materials and workmanship for 5 years from the date of original purchase (except as noted below). During the stated 5-year period, Bayer Diabetes Care shall, at no charge, replace a unit found to be defective with an equivalent or current version of the owner's model.

Limitations of Warranty: This warranty is subject to the following exceptions and limitations:

1. A 90-day warranty only will be extended for consumable parts and/or accessories.
2. This warranty is limited to replacement due to defects in parts or workmanship. Bayer Diabetes Care shall not be required to replace any units which malfunction or are damaged due to abuse, accidents, alteration, misuse, neglect, maintenance by someone other than Bayer Diabetes Care, or failure to operate the instrument in accordance with instructions. Further, Bayer Diabetes Care assumes no liability for malfunction or damage to Bayer Diabetes Care instruments caused by the use of reagents other than reagents (i.e., CONTOUR® test strips) manufactured or recommended by Bayer Diabetes Care.
3. Bayer Diabetes Care reserves the right to make changes in design of this instrument without obligation to incorporate such changes into previously manufactured instruments.

4. Bayer Diabetes Care has no knowledge of the performance of the CONTOUR® USB blood glucose meter when used with any test strips other than CONTOUR® test strips, and therefore makes no warranty of the performance of the CONTOUR USB meter when used with any test strips other than CONTOUR test strips or when the CONTOUR test strip is altered or modified in any manner.

BAYER DIABETES CARE MAKES NO OTHER EXPRESS WARRANTY FOR THIS PRODUCT. THE OPTION OF REPLACEMENT, DESCRIBED ABOVE, IS BAYER DIABETES CARE'S ONLY OBLIGATION UNDER THIS WARRANTY.

IN NO EVENT SHALL BAYER DIABETES CARE BE LIABLE FOR INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES, EVEN IF BAYER DIABETES CARE HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

For warranty service: Purchaser must contact the Support Group of Bayer Diabetes Care, by calling toll free 0845 600 6030 (UK)/ 1 890 920 111 (Ireland), for assistance and/or instructions for obtaining service of this instrument.

Patents: The system described herein is covered by one or more of the following US patents: 5,120,420; 5,266,179; 5,582,697; 5,620,579; 5,723,284; 5,954,738; 6,059,946; 6,451,040; 6,599,406; 6,827,829; 6,911,131; 7,232,510; as well as pending applications and international equivalents.

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